Docket 5

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June 8, 2004

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VIA UPS NEXT DAY

Claudia V. Grillo
Office of Regulatory Policy (HFD-013)
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Re: FDA Docket No. 01E-0032
Our Docket No. 27301-28066.00
Patent Term Extension for Visudyne
U.S. Patent No. 5,095,030

Dear Ms. Grillo:

Enclosed is a copy of the Revised Application for Extension of Patent Term and accompanying documents, which we mailed to the U.S. Patent and Trademark Office on April 6, 2004, in connection with the above matter.

Thank you for following up on this.

Best regards,

Kate Murashige

Kate H. Murashige

KHM/mc
Enclosures
cc: Jennifer Kaufman-Shaw (letter only)

sd-203276

2001E-0032

APP 2

Atty Docket No.: 273012806600

Inventor: Julia G. LEVY et al.

Patent No.: 5,095,030 **Issue Date:** March 10, 1992
Title: WAVELENGTH-SPECIFIC CYTOTOXIC AGENTS

Documents Filed:

Transmittal (1 page)

Revised Application for Extension of Patent Term (8 pages)

Exhibits A through B (279 pages)

Copy of Declaration Under 37 C.F.R. 1.740(b) (2 pages)

Certification Under 37 C.F.R. 1.740 (a)(16) (1 page)

(All documents submitted in duplicate)

Via: First Class Mail
Sender's Initials: KHM/mc **Date:** April 6, 2004

Atty Docket No.: 273012806600

Inventor: Julia G. LEVY et al.

Patent No.: 5,095,030 **Issue Date:** March 10, 1992
Title: WAVELENGTH-SPECIFIC CYTOTOXIC AGENTS

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Via: First Class Mail
Sender's Initials: KHM/mc **Date:** April 6, 2004

NXM

I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail, in an envelope addressed to: Mail Stop Patent Ext., Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.

Dated: April 6, 2004 Signature: Marian Christopher

(Marian Christopher)

PATENT
Docket No. 273012806600

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re U.S. Patent 5,095,030

Issued March 10, 1992

To: Julia G. Levy, *et al.*,

For: WAVELENGTH-SPECIFIC CYTOTOXIC AGENTS

REVISED APPLICATION FOR EXTENSION OF PATENT TERM UNDER 35 U.S.C. § 156

Mail Stop Patent Ext.
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

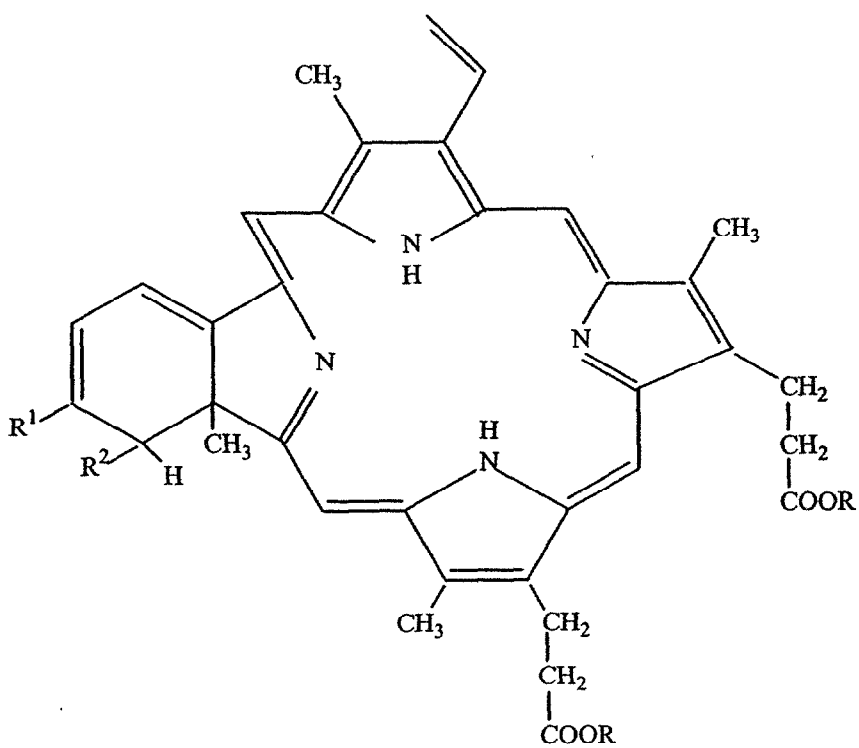
This is a revised petition for an extension of the term of U.S. patent 5,095,030. The original application was filed 12 June 2000, within 60 days of the approval of VISUDYNE™, having an active ingredient, verteporfin, covered by the claims of U.S. patent 5,095,030. Since the original application was filed, it has been called to applicant's attention that an earlier submission to the FDA for the same active ingredient, administered in the same way but for a different indication, was relevant to the calculation of extended patent term. Applicant understands that the FDA, in its calculations, would take account of these earlier studies in any event; however, to assist in drawing the attention of the FDA to these studies, the herein revised application is submitted.

sd-192671

The applicant, University of British Columbia of Vancouver, British Columbia, Canada, represents that it is the assignee of the entire right, title and interest in and to U.S. Patent No. 5,095,030 (hereinafter "the Patent") granted to the University of British Columbia on March 10, 1992 by virtue of assignments made by the inventors and recorded at reel/frame 5180/0357 on 26 October 1989. This Patent is exclusively licensed to QLT PhotoTherapeutics, Inc. which has conducted the studies leading to approval by the Food and Drug Administration of the approved drug VISUDYNE™ verteporfin and will commercialize the approved product.

Applicant hereby requests an extension of term of the Patent under 35 U.S.C. § 156. The following information as required by 37 C.F.R. § 1.740 is set forth below:

1. The approved product is VISUDYNE™ verteporfin for injection. The active ingredient is of the formula



wherein one R is methyl and the other is H, and R^1 and R^2 are both carboxymethyl. The active ingredient is formulated in a liposomal carrier. The detailed composition, which is a powder to

be taken up into an aqueous solution for injection, contains (mg/vial) 15.00 verteporfin, 690.00 lactose monohydrate, 70.50 dimyristoyl phosphatidylcholine, 48.75 egg phosphatidyl glycine, 0.15 ascorbyl palmitate, 0.015 butylated hydroxy toluene.

2. The approved product was subject to regulatory review under the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355.

3. The approved product received permission for commercial marketing or use under § 505 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355) on April 12, 2000.

4. The active ingredient in the approved product is verteporfin. The active ingredient has not been previously approved for commercial marketing or use under the Federal Food, Drug and Cosmetic Act or under any other U.S. law.

5. The original application was submitted within the 60-day period permitted for submission pursuant to 37 C.F.R. § 1.720(f). The last day for such submission under this section was June 12, 2000 (June 11, the 60th day, being a Sunday).

6. The complete identification of the Patent for which extension is being sought is as follows:

Inventors: Julia G. Levy, David Dolphin, Jack K. Chow and Ethan Sternberg

Patent No. 5,095,030

Date of Issue: March 10, 1992

Date of Expiration: April 24, 2007.

7. A copy of the patent for which extension is sought is attached as Exhibit A.

8. A Terminal Disclaimer was filed in regard to this patent setting its term to expire on April 24, 2007. A copy of said Terminal Disclaimer is attached hereto as Exhibit B. No Reexamination Certificate has issued in this patent. The first Maintenance Fee was due on

September 10, 1995, and was timely paid. The second Maintenance Fee was due on September 10, 1999, and was timely paid and the third Maintenance Fee was due on September 10, 2003, and was timely paid. A receipt for the most recent fee (year 11) is enclosed as Exhibit C.

9. The Patent claims the approved product as a composition of matter, Claim 1 includes the approved product when the compound is of formula 3 and when each of R^1 and R^2 is carbalkoxy, specifically, carbomethoxy, R^4 is $CHCH_2$, and each R^3 is carboxyalkyl (2-6C) or an ester thereof, specifically wherein one of R^3 is carboxyethyl and the other R^3 is carbomethoxy ethyl.

The approved product is also covered by claim 3 as it depends from claim 1 The limitation wherein R^1 and R^2 are carbalkoxy includes the approved product. Claim 4, dependent on claim 3 further narrows the definition of R^1 and R^2 to the carbomethoxy embodiment included in the approved product. Claim 5 as dependent on claim 1 and claim 6 as dependent on claim 3 also cover the approved product as R^3 is defined as CH_2CH_2COOH or a derivative, including an ester thereof. Claims 7 and 8 also include the approved product as the scope is limited to that where the compound is of formula 3 (or 4). Claim 11 provides the structure of BPD-MA specifically in column 32 although in a somewhat generic form. Claim 12 as dependent on claim 1 is simply directed to a pharmaceutical composition.

10. The relevant dates and information pursuant to 35 U.S.C. § 156(g) in order to enable the Secretary of Health and Human Services to determine the applicable regulatory review periods are as follows:

(a) The effective date of the investigational new drug (IND) application for the approved product for the indication finally approved (age-related macular degeneration) was January 16, 1995 and the application was assigned IND No. 47,102 on January 23, 1995.

(b) A new drug application (NDA) for the approved product was submitted on August 14, 1999 as NDA Application No. 21-119.

(c) NDA No. 21-119 as approved on April 12, 2000.

(d) The approval of VISUDYNE™ also relied on data of a previous IND for the same drug, also administered by injection, directed to the treatment of skin cancer, which was accepted at the FDA on 17 June 1991 and assigned IND No. 37,129. Diligent pursuit of studies related to this IND were continued until 5 June 1996, as shown in the attached Exhibit E. Copies of reports related to a verteporfin for injection (the route of administration in the approved indication) are also enclosed as Exhibits F and G. Thus, the activities conducted under IND No. 37,129 overlapped the activities conducted under IND No. 47,102 between January 23, 1995, and June 5, 1996.

11. During the applicable regulatory review period, applicant diligently undertook to satisfy the requirements of the Federal Food, Drug and Cosmetic Act as applied to the approved product in order to obtain regulatory approval to sell the approved product. The activities and the dates applicable to such activities are summarized in Exhibits D, E, F and G.

12. In the opinion of applicant, the Patent is eligible for extension under 35 U.S.C. § 156 for a period of 5 years until April 24, 2012, which period was determined in accordance with 37 C.F.R. § 1.775 as follows:

(a) In accordance with 37 C.F.R. § 1.775(c) the length of the regulatory review period for the approved product (a human drug) is 1,929 days. This was calculated as the sum of:

(i) The number of days in the period beginning on the date of exemption under 35 U.S.C. § 156(g)(1)(B)(i) from June 21, 1991 (the effective date of IND No. 37,129) until August 24, 1999 (NDA 21-119 submission date) which is 2,986 days; and

(ii) The number of days in the review period under 35 U.S.C. § 156(g)(1)(B)(ii) from August 24, 1999 (NDA submission date) until April 12, 2000 (NDA approval date) which is 232 days.

Thus, the regulatory review period under 37 C.F.R. § 1.775(c) is 3,218 days.

(b) In accordance with 37 C.F.R. § 1.775(d) the term of the Patent as extended is determined as follows:

(i) The sum of the following is to be subtracted from the regulatory review period as determined above:

- The number of days in the regulatory review period which were on or before the date on which the Patent issued which is 262 days (June 21, 1991 to March 10, 1992).
- The number of days in the regulatory review period wherein applicant did not act with due diligence, which is zero (0).
- One-half the number of days remaining in the period defined by paragraph (c)(1) of 37 C.F.R. § 1.775 that has been reduced in accordance with the two items above, which is 1,362 days ((2,724/2; (2,986 - 262 = 2,724).

(ii) The balance of the regulatory review period after subtraction of the days required by 37 C.F.R. § 1.775(d)(1) is 1,856 days (3,218-1,362).

(iii) The date of expiration of the Patent as extended based on the calculations above would thus be April 24, 2007, plus 1,856 days.

(iv) Since 1,856 days is more than the statutory limit of a five-year total extension; the expiration date would thus be five years, or April 24, 2012, which is earlier than the maximum 14-year extension from the date of NDA approval which would be April 12, 2014.

(v) Accordingly, the expiration date of the Patent extended in accordance with this petition would be April 24, 2012.

13. Applicant and the undersigned acknowledge a duty to disclose to the Commissioner of Patents and Trademarks and to the Secretary of Health and Human Services any information which is material to the determination of entitlement to the extension sought.

14. The prescribed fee for receiving and acting upon the Application for Extension was charged in the original application ($1,120.00). This fee was charged to **Deposit Account**

No. 03-1952 when the original application was filed. The Commissioner is authorized to charge any required additional amounts to this account.

15. The address for applicant's representative has also changed since the date of the original application. Please direct all inquiries and correspondence relating to this Application for Patent Term Extension to:

Kate H. Murashige, Esq.
Morrison & Foerster, LLP
3811 Valley Centre Drive, 5th Floor
San Diego, CA 92130
Phone: (858) 720-5112.

16. A duplicate of the application papers certified as such is enclosed.

17. A list of exhibits is enclosed.

18. A copy of a declaration meeting the requirements of 37 C.F.R. § 1.740(b) submitted with the original application is enclosed.

Dated: April 6, 2004

Respectfully submitted,

UNIVERSITY OF BRITISH COLUMBIA

By: Kate H. Murashige
Kate H. Murashige
Reg. No. 29, 959

List of Exhibits

Exhibit A is a copy of U.S. patent 5,095,030.

Exhibit B is a copy of a terminal disclaimer submitted in respect of this patent.

Exhibit C is an updated maintenance fee statement.

Exhibit D is a correspondence table regarding IND No. 47,102 and NDA application No. 21-119.

Exhibit E is a correspondence table with regard to IND No. 37,129.

Exhibit F is a study report for verteporfin for injection in treatment of malignant cutaneous lesions.

Exhibit G is a study report of verteporfin for injection for the treatment of psoriasis.

COPY

PATENT
Docket No. 273012806600

CERTIFICATE OF MAILING BY "FIRST CLASS MAIL"

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on June 12, 2000.

Joy Day

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re U.S. Patent 5,095,030

Issued March 10, 1992

To: Julia G. Levy, *et al.*,

For: WAVELENGTH-SPECIFIC CYTOTOXIC AGENTS

DECLARATION UNDER 37 C.F.R. § 1.740(b)

Assistant Commissioner for Patents & Trademarks
Box Patent Extension
Washington, D.C. 20231

Dear Sir:

I, Kate H. Murashige, declare as follows:

1. I am an attorney authorized to practice before the U.S. Patent and Trademark Office and have general authority from University of British Columbia of Vancouver, British Columbia, Canada, the owner of U.S. Patent No. 5,095,030 (hereinafter, "the Patent"), for which extension is sought, to act on its behalf in patent matters.

2. I have reviewed and understand the contents of the application being submitted pursuant to 37 C.F.R. § 1.740.

3. I believe the Patent is subject to extension pursuant to 37 C.F.R. § 1.710.

4. I believe an extension of the length claimed is justified under 35 U.S.C. § 156 and the applicable regulations.

5. I believe that the Patent for which extension is being sought meets the conditions for extension of the term of a patent as set forth in 37 C.F.R. § 1.720.

6. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

6/12/00
Date

Kate H. Murashige
Kate H. Murashige
Registration No. 29,959

PATENT
Docket No. 273012806600

CERTIFICATE OF MAILING BY "FIRST CLASS MAIL"

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Patent Ext., Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on April 6, 2004.

Marian Christopher

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re U.S. Patent 5,095,030

Issued March 10, 1992

To: Julia G. Levy, *et al.*,

For: WAVELENGTH-SPECIFIC CYTOTOXIC AGENTS

CERTIFICATION UNDER 37 C.F.R. § 1.740(a)(16)

Mail Stop Patent Ext.
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

Dear Sir:

I hereby certify that the attached photocopy is an exact duplicate of the Revised application for Extension of the Term of U.S. Patent No. 5,095,030 under 35 U.S.C. § 156 including its attachments and supporting papers mailed to the U.S. Patent and Trademark Office on this date.

Dated: April 6, 2004

Respectfully submitted,

By: _____
Kate H. Murashige
Registration No. 29,959

Morrison & Foerster LLP
3811 Valley Centre Drive
Suite 500
San Diego, CA 92130-2332

Telephone: (858) 720-5112
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sd-193045